

**SUMMARY OF THE  
QUALITY SYSTEMS COMMITTEE MEETING  
JUNE 2, 1999**

The Quality Systems (QS) Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met by teleconference on June 2, 1999, at noon Eastern Daylight Time (EDT). The meeting was led by its chair, Mr. Joe Slayton of the U.S. Environmental Protection Agency (USEPA) Region III. A list of action items is given in Attachment A. A list of participants is given in Attachment B. The list of parking lot issues is currently empty (Attachment C). Attachment D is a listing of frequently asked questions. Attachment E presents the QS Committee approach to handling comments, and commenter template. Attachment F is a listing of the QS's guiding principles for reviewing comments and the standard. *The purpose of the meeting was to review action items from the previous teleconferences and discuss additional comments received by the committee during May 1999.*

**REVIEW OF ACTION ITEMS FROM THE PREVIOUS MEETING**

The QS Committee reviewed the action items from the previous meeting by teleconference, which was held on May 26<sup>th</sup>. All items had been completed or addressed except item #3 which concerns discussion of the glossary with the NELAC Board of Directors. This item was carried over as an action item for the next meeting to be held on June 2, 1999. Ms. Sylvia Labie (NELAC Board Member) reported that the board and Ms. Betsy Dutrow (NELAC Executive Secretary) have recommended that the QS Committee and Program Policy and Structure Committee meet to develop a consensus Glossary. Mr. Slayton will contact Dr. Marcia Davies of the Program Policy and Structure Committee to discuss reconciling the differences in the NELAC and QS glossaries. Glossary entries where conflicts exist should be identified and may need to be withdrawn from the ballot at NELAC V. When the differences between the two glossaries are reconciled, the withdrawn terms can be added. The QS Committee plans to drop the glossary from Chapter 5 once these terms have been included in the NELAC Glossary. However, the QS Committee feels it will be necessary to maintain some oversight of the glossary to ensure terms important to Chapter 5 are included.

**TOPICS OF DISCUSSION**

**Review Whole Effluent Toxicity (W.E.T.) Comments (Mr. Jackson/SAIC)**

The discussion and consensus decision of the committee are listed in Attachment G. Note sections 5-7 of the comments were discussed on June 2, 1999. Changes to the language in Chapter 5 proposed at this teleconference are reflected in version 5.10.11 of the standard, which is consistent with the attached comments to Mr. Larry Jackson (SAIC). However, to avoid confusion within NELAC, since version 5.10.7 is the version provided for NELAC 5 voting, 5.10.11 is only being circulated within the QS Committee at this time (not attached to these minutes and will not be posted on the NELAC Website).

## Ethics

The committee reviewed language in Sections 5.5.2 and 5.6 related to fraud prevention. The committee agreed on the following actions:

- Section 5.5.2.u: new language accepted
- Section 5.5.3.2, ¶2: Add “Develop and implement ~~A~~ a proactive program approach....” to paragraph 2 and move to become Section 5.6.2.h.
- Glossary Add term for “Fraud Prevention”
- Section 5.6.2.c).3) Add period to end of sentence

## Other changes in text for Chapter 5 are as follows:

- Section 5.9.4.2.1.a). Add “The details...including calculations, integrations, acceptance criteria, and associated statistics...”.
- Section 5.9.4.2.1.h) Line two, change “concentratins” to “concentrations”
- Section 5.9.4.2.1.i) There was considerable discussion on the requirement for two calibration points. Some Committee members questioned whether a blank might be used as one of the two required points. There was general agreement that the required two points should be in addition to a blank. Language to make clear the intent of this requirement will have to be drafted. This issue will need to be identified before balloting at NELAC V as a “Red Tag” items coming from comments and proposed revisions received later than version 5.10.07.
- Appendix D.1.1.a).1).ii) Sentence below ii) should be *strikeout* and not *double underline* [both are currently shown]

## APPENDIX D.4 - RADIOCHEMICAL ANALYSIS

A revised Appendix D.4 on Radiochemical Analysis was submitted by Mr. Donovan Porterfield and accepted by the committee. Mr. Porterfield will rewrite sections of this appendix with language to resolve conflicts with earlier drafts and Mr. Slayton will identify the issues requiring changes from the 5.10.07 draft of Chapter 5. These differences will need to be identified before balloting at NELAC V as later than version 5.10.07.

## NEXT MEETING

The next meeting by teleconference is scheduled for June 17, 1999 from 1 p.m. to 5 p.m. EDT and the telephone number is 202-269-4529, access code 7254#.

**ACTION ITEMS  
QUALITY SYSTEMS COMMITTEE  
JUNE 2, 1999**

<b>Item No.</b>	<b>Action Item</b>	<b>Date to be Completed</b>
1.	Mr. Slayton to contact Dr. Davies of Program Policy and Structure Committee to discuss ways to combine QS Glossary with Program Policy and Structure Glossary and how to present related issues at NELAC V.	June 24, 1999
2.	Mr. Porterfield to revise Appendix D.4 (Rad-Chem) to incorporate new language.	June 24 1999
3.	Mr. Slayton will identify “Red Tag” issues for Appendix D.4 (Rad-Chem) for the voting process at NELAC V.	June 24, 1999
4.	Mr. Slayton to update the “Comments Table” to indicate current status and homework assignments-and distribute to committee	June 24, 1999
5.	Mr. Slayton to update Chapter 5 rev. from 5.10.10 to 5.10.11 and circulate within the committee.	June 24, 1999

**PARTICIPANTS  
QUALITY SYSTEMS COMMITTEE  
JUNE 2, 1999**

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**PARKING LOT ITEMS/ISSUES AND  
FREQUENTLY ASKED QUESTIONS  
QUALITY SYSTEMS COMMITTEE  
JUNE 2, 1999**

Items/issues will remain in the Parking Lot until they are completed.

(There are not any items/issues outstanding at this time.)

## **Some Frequently Asked Questions Concerning NELAC QS (Chapter 5): Attachment D**

**1. Question:** If a mandated method (required by EPA or State Authority) is less stringent than the QS standards what do I follow?

**Answer:** The most restrictive/demanding.

**2. Question:** Do the QS standards require the use of any specific method?

**Answer:** No. QS does not require the use of a specific method/s. Chapter 5 allows the user to select an appropriate method. However, regulatory agencies may mandate the use of a specific method (See also Question 3).

**3. Question:** Do the QS standards allow for the use of the PBMS approach?

**Answer:** Yes. However, the QS standards may include additional QS checks/requirements (considered by NELAC to be essential) than those associated with a PBMS method for a given project. Such additional requirements would also apply to conventional or non-PBMS methods as well.

**4. Question:** Do the QS standards apply to small laboratories?

**Answer:** Yes. The standards include essential QC procedures and are applicable to environmental laboratories regardless of size and complexity. It is suggested that the amount of effort that will be required to attain the standards will be dependent on whether the laboratory already is operating under a quality system (with established and documented SOPs and QC procedures) more than upon the size of the laboratory.

**5. Question:** If my laboratory is measuring high level concentrations and is set-up (perhaps even optimized) to analyze at such levels and is only interested in whether a high level regulatory limit is exceeded, why do I have to determine a detection limit?

**Answer:** A detection limit is considered essential to verify (confirm and document) that the laboratory is actually able to detect and measure at the regulatory or decision limit. Detection limit determinations are also considered an important consideration with regard to the quantitation range selection particularly with regard to the choice of the concentration of the lowest calibration standard. Changes to the standard will be proposed at the January 1999 Interim Meeting, which no longer specify that the MDL (40 CFR Part 136) procedure be employed, unless it is mandated by the test method or applicable regulation. In the proposed revision, the term "detection limit" may not be the lowest concentration level attainable by a given analytical method, but rather that it is a concentration that is actually measurable (and verified) using the procedures, e.g., equipment, analytical method, routinely employed for sample analyses (could be relatively high concentration). The detection level should be appropriate or relevant for the intended use of the data. In some cases this will of necessity be the lowest concentration level attainable, e.g., low level drinking water or wastewater permit limits.

**6. Question:** Why are we revisiting the calibration and detection parts of the standards?

**Answer:** At NELAC IV the Quality Systems Committee received numerous comments that the calibration and detection parts of the standards were too prescriptive and were not consistent with a PBMS environment. The Committee has attempted to propose changes to the calibration and detection parts of the standards that provide essential elements for those two quality system standards and that will support the anticipated needs of PBMS. The Committee believes the proposed language is less prescriptive (i.e., more flexibility), yet hopefully still ensures the quality of the analytical data.

In making these proposed changes the Committee has attempted to balance the need for more flexibility in the standards with the desire to not go too far and introduce excessive flexibility that could prove to be too vague or ill-advised. The Committee is currently discussing and considering its proposed language and public comments on the proposed language changes. The Committee is committed to assuring that the NELAC Quality Systems standards provide a foundation for PBMS implementation.

**7. Question:** Several States have indicated that it is very desirable that a laboratory already be actively analyzing samples for a particular program and by a method for which they want to be accredited. However, these same states have relayed that this ideal scenario is often not the case, as a laboratory may request accreditation in attempts to expand their scope of analytical services or in order to satisfy contractual requirements. These states ask: How will the QS standards help ensure that laboratories will have sufficient data for an onsite assessment especially given the proposed changes to the MDL section?

**Answer:** The MDL, section D.1.4, in the 1998 NELAC standards has a requirement that “MDLs” be determined initially (40 CFR Part 136, Appendix B) and be verified yearly by the analysis of at least one clean matrix sample spiked at the current reported MDL. Under the proposed revision to Section D.1.4, “Detection Limits” are to be determined initially and each time there is significant change in the test method or instrument type. The proposed standard still requires “MDL” if required in the mandated test method or applicable regulation. If the MDL is not required a “detection limit” must still be determined. Therefore the new section D.1.4 requirements should still help assure that performance data will be available for review by inspectors. In addition, laboratories are required to successfully complete two out of three PT samples yearly and this data would be available for review, as per section 5.5.4 and Chapter 2). However, under the current PT requirements this may only include one method of multiple methods employed by a laboratory for a given parameter group, e.g., metals.

Laboratories also must perform an Initial Demonstration of Analytical Capability (5.10.2.1, D.1.3 Method Evaluation and Appendix C). This data would be available for on-site review. Also note that the QS committee plans to expand Appendix C (IDC) procedures prior to NELAC V to make it applicable to methods for which spiking is difficult or impossible, e.g., Total Suspended Solids, which should further ensure that performance data is available for review.

In addition under Section 5.6.2.3.c. of QS, the Laboratory Management must ensure that the training of personnel is kept up-to-date, which includes a analyst certification to perform the most recent version of the test method (the approved method or standard operating procedure) and documentation of continued proficiency by at least one of the following once per year: i. acceptable performance of a blind sample (single blind to the analyst); ii. another initial demonstration of method capability; iii. successful analysis of a blind performance sample on a similar test method using the same technology; iv. at least four consecutive laboratory control samples with acceptable levels of precision and accuracy; vi if i-iv cannot be performed, analysis of authentic samples that have been analyzed by another trained analyst with statistically indistinguishable. These requirements should further help assure performance data is available on-site for review.



## **QS Approach: Comments Received and QS Response:**

1. A form letter will be sent to each commentor notifying them of receipt of the comment and of the QS's approach to reviewing comments and associated updates to the standards.
2. QS will consider the comments in the order received.
3. A QS committee member will be designated as the lead on each set (or up-set) of the comments from each commentor, who will provide written comments and who will lead a discussion with the full committee on any proposed changes to the standards (including providing the proposed standard language).
4. Proposed changes to the standards will be captured in the QS meeting minutes which are posted on the NELAC Web page.
5. All comments and written responses will be attached to QS meeting minutes.
6. No colors to be used in the comments nor in the response. Use double underlines for additions and strike-outs for removal of items.
7. All comments are to be provided in WordPerfect or rich text format using the following the following table:

**GUIDING PRINCIPLES/REVIEW CRITERIA**

The QS Committee established a set of criteria by which to evaluate the requirements specified in Chapter 5. The standards in Chapter 5 should meet the criteria listed below:

**Flexible:**

Allow laboratories freedom to use their experience and expertise in performing their work and allow for new and novel analytical methods and approaches, (e.g., Performance Based Measurement System [PBMS]). That the standards specify the “What” and avoid where possible the “How To”, (e.g., control limits must be developed to determine if a QC check result is acceptable, the standards do not specify how the laboratory is to determine these limits).

**Auditable:**

Sufficient detail is included so that the accrediting authorities evaluate laboratories consistently and uniformly.

**Practical/Essential:**

The standards are necessary QA policies and QC procedures and that these standards should not place an unreasonable burden upon laboratories.

**Widely Applicable:**

International scope- consistent with ISO Guide 25. Represent QA policies, which establish essential QC procedures, that are applicable to environmental laboratories regardless of size and complexity.

**Appropriate For The Use of the Data:**

Helps ensure that associated environmental data is of known quality and that the quality is adequate for the intended use of the data.

<b>Comment ID #:</b> , <b>Source of Comments (Name):</b> <b>QS Lead on Response (Name):</b>			
<b>Standard Rev. #   SECTION#</b> <b>and QS Standard Narrative</b> <b>(To Filled in by Commentor)</b>	<b>COMMENTwith Rationale to QS</b> <b>(To Be Filled in by Commentor)</b>	<b>QS Leader Provided</b> <b>Proposed Change</b> <b>(Commentor Leave</b> <b>Blank)</b>	<b>RATIONAL</b> <b>(from QS Leader)</b> <b>(Commentor Leave</b> <b>Blank)</b>
	<b>New Wording for Standard</b>  <b>(To Be Filled in by Commentor)</b>		

## Appendix G:

### Review comments on NELAC Quality System Std., rev 10.1 dated 1/13/99

Commentor: Larry P. Jackson, e-mail to [lpjackson@MSN.com](mailto:lpjackson@MSN.com), tel. 603/924-6852

Comment #	Section #	Current Text	Suggested Revision And Rational	QS Leader Proposed Change	Rational for Change
<i>Comments #1 to 9 provide suggested revisions to specific items in the current draft standards (revs 9 and 10.1). Comments #10 and 11 address larger issues that needed more discussion. The latter comments are discussed in narrative fashion to place the comments in the larger perspective to convey my concerns. As part of each discussion, suggested language for insertion in the standard is provided. If these suggestions are accepted in concept, I will be glad to work with the appropriate committee member to work out language acceptable to committee if the suggested text is inadequate.</i>					
1	5.6.2.c) v.	v. If i-iv cannot be performed, analysis of authentic samples that have been analyzed by another trained analyst with statistically identical results.	v. If i-iv cannot be performed, analysis of authentic samples that have been analyzed by another trained analyst <i>with statistically similar results for the mean value and precision.</i> <b>Rational:</b> It is not probable that two analysts will get identical results. To establish equivalency of ability, the second analyst should be able to generate a mean value within $\pm 2\sigma$ of the original analyst's value and achieve similar values of relative standard deviation (RSD).	Have already made a change to address this point.	Agree with rational
2	5.9.4.2.1a)	The details of the initial instrument calibration procedure, calculations and associated statistics must be included or referenced in the test method SOP.	Add the following sentences: <i>Any referenced material must be retained in the office of the quality assurance officer where it can be accessed by the staff as necessary. The material included in the method SOP shall be subject to the same degree of technical review and approval as the SOP.</i> <b>Rational:</b> All material included in an SOP by reference should be reviewed using approved document control procedures to assure it meets the requirements for technical application and defensibility established in the laboratory QS.	When initial instrument calibration procedures are referenced in the test method, then the referenced material must be retained by the laboratory and be available for review.	Agree with proposal and rational
3	5.9.4.2.1b)	Sufficient raw data records must be retained to permit reconstruction of the initial instrument calibration, e.g., calibration date, test method, instrument, analysis date, each analyte name, concentration and response, calibration curve or response factor.	Sufficient raw data records must be retained to permit reconstruction of the initial instrument calibration, e.g., <i>analyst name or initials</i> , calibration date, test method, instrument, analysis date, each analyte name, concentration and response, calibration curve or response factor. <b>Rational:</b> The name of the performing analyst is a necessary item of information to reconstruct the calibration event. This will allow a reviewer to determine if the analyst was qualified on the method at the time they performed the calibration.	Add "analyst's or operator's initials or signature"	This is already addressed in 5.12.3.3.f but it would benefit it to also be stated in 5.5.4.2.1.b.
4	5.9.4.2.1d)	All initial instrument calibrations must be verified with a standard obtained from a second source.	Add the following sentence: <i>The laboratory shall have a written procedure detailing the technical basis used to verify the initial calibration.</i> <b>Rational:</b> All critical steps in the quality process, such as verification, must be documented by written procedure otherwise, there is no standard against which adequate performance can be demonstrated.	No Change	Already addressed in 5.9.4.2.1

5	5.9.4.2.1e)	Criteria for the acceptance of an initial instrument calibration must be established, e.g., correlation coefficient and relative percent difference.	<p>Criteria for the acceptance of an initial instrument calibration must be established <i>in the method SOP</i>, e.g., correlation coefficient and/or relative percent difference <i>of analyte response factors within and/or between the concentration level(s) used to establish calibration</i>.</p> <p><b>Rational:</b> All critical steps in the quality process, such as verification, must be documented by written procedure otherwise, there is no standard against which adequate performance can be demonstrated. The use of the and/or conjunctive phrase allows the laboratory to establish calibration at a single concentration level. This situation applies when the client is only interested in a pass/fail decision at a de minimus level. It is unnecessarily complex and costly to calibrate across a range when only one level is used in the decision. This applies to all types of analysis but can be easily illustrated by the determination of pH. This measurement is often used in a simple pass/fail determination at a fixed level.</p>	<p>Change:</p> <p>a) The details of the initial instrument calibration procedures including calculations, integrations, and associated statistics must be included or referenced in the test method SOP.</p> <p>to:</p> <p>a) The details of the initial instrument calibration procedures including calculations, integrations, <b>acceptance criteria</b>, and associated statistics must be included or referenced in the test method SOP.</p>	<p>a) is where the SOP is discussed and while this change may not be necessary it does help stress the need for acceptance criteria.</p> <p>Do not incorporate the phrase <i>/or</i> . This is not the appropriate way or place in the standard to address single point standards. The existing text, correlation coefficient and relative percent difference, is offered for example only as defined by the use of “e.g.”</p> <p>Do not add <i>of analyte response factors within and/or between the concentration level(s) used to establish calibration</i>. this would only apply to certain types of analysis. it would not be relevant to the example offered of pH. Single point calibration of a pH meter, particularly at pH 7 for example would not be appropriate.</p>
6	5.9.4.2.1g)	If the initial instrument calibration results are outside established acceptance criteria, corrective actions must be performed. Data associated with an unacceptable initial instrument calibration shall not be reported.	<p>If the initial instrument calibration results are outside established acceptance criteria, corrective actions must be performed. Data associated with an unacceptable initial instrument calibration <del>shall not be reported</del> <i>must be reported as having less certainty, e.g. defined qualifiers, flags, or described in the case narrative</i></p> <p><b>Rational:</b> Not reporting results is overly restrictive. The results may have been determined on the only sample material available are therefore irreplaceable. Reporting, with appropriate qualifiers and explanation in the case narrative adheres to the NELAC QS principles.</p>	no change	<p>If the availability of samples were so limited to make the samples so unique and valuable, it should have been the responsibility of the laboratory to assure that the initial calibration results met the required acceptance criteria before the limited quantities of samples were wasted.. However, in all cases, the raw data of the failed calibration and any analysis should be retained.</p>

7	5.9.4.2.1i.)	Current text OK	As written, the QS std makes no provision for calibration around a single point. Suggest adding the following text: <i>A single point calibration can be established if it meets the client's data needs. The method SOP must specify how the confidence level for the single point calibration is established, e.g. replicate analysis sufficient to establish the standard deviation at the target level.</i>	no change	<p>The text in the current version of the standard is appropriate:</p> <p>:</p> <p>i) The minimum number of concentration points for performing an initial instrument calibration is two. The laboratory must have a standard operating procedure for determining the number of points for establishing the initial instrument calibration.</p> <p>Single point calibrations may be possible for some continuing calibration instances, but the initial calibration should always be at least two points.</p> <p>See Text Below</p>

(Text from 5.10.3:)

#### 5.9.4.2.1 Initial Instrument Calibration:

The following items are essential elements of initial instrument calibration:

- a) The details of the initial instrument calibration procedures including calculations, integrations, and associated statistics must be included or referenced in the test method SOP.
- b) Sufficient raw data records must be retained to permit reconstruction of the initial instrument calibration, e.g., calibration date, test method, instrument, analysis date, each analyte name, concentration and response, calibration curve or response factor.
- c) Sample results must be quantitated from the initial instrument calibration and may not be quantitated from any continuing instrument calibration verification.

- d) All initial instrument calibrations must be verified with a standard obtained from a second source and traceable to a national standard, when available.
- e) Criteria for the acceptance of an initial instrument calibration must be established, e.g., correlation coefficient and relative percent difference.
- f) Results of samples not bracketed by initial calibration standards (within calibration range) must be reported as having less certainty, e.g., defined qualifiers or flags or explained in the case narrative.
- g) If the initial instrument calibration results are outside established acceptance criteria, corrective actions must be performed. Data associated with an unacceptable initial instrument calibration shall not be reported.
- h) Calibration standards must include concentrations at or below the regulatory limit/decision level, if these limits/levels are known by the laboratory, unless these concentrations are below the laboratory's demonstrated detection limits (See D.1.4 Detection Limits)
- ii) The minimum number of concentration points for performing an initial instrument calibration is two. The laboratory must have a standard operating procedure for determining the number of points for establishing the initial instrument calibration.

alternate text

- iii) The laboratory must have a standard operating procedure for determining the number of points for establishing the initial instrument calibration. This standard operating procedure must include criteria for single point calibration curves. The minimum number of concentration points for performing an initial instrument calibration is two unless the criteria for single point calibration curves is met.



## Review comments on NELAC Quality System Std., rev 10.1 dated 1/13/99

Commentor: Larry P. Jackson, e-mail to [lpjackson@MSN.com](mailto:lpjackson@MSN.com), tel. 603/924-6852

Comment #	Section #	Current Text	Suggested Revision And Rational	QS Leader Proposed Change	Rational for Change
8	5.12.1a)	The records shall include the identity of personnel involved in <i>sampling</i> , preparation, calibration or testing.	The records shall include the identity of personnel involved in <i>sample receipt</i> , preparation, calibration or testing.  <b>Rational:</b> This std. applies only to the laboratory. It is not appropriate or enforceable to include requirements on activities outside of the lab's area of responsibility. As currently written, an audit would have to find the lab in violation of the NELAC QS std. yet they are not in position to implement a corrective action.	The records shall include the identity of personnel involved in <u>sampling</u> , <u>sample receipt</u> <del>sampling</del> , preparation, calibration or testing.	The current language seems inappropriate for a requirement related to sample receipt. The "Sample Acceptance Policy" subject is addressed in 5.11.2 and the specific requirement for recording the "collector's name" is in 5.11.2.a.
9	5.12.3.2c)	Records that are stored or generated by computers or personal computers (PCs) shall have hard copy or write-protected backup copies.	Add the following sentence: <i>The laboratory must retain the ability to read and print out copies of all records that are retained in electronic format.</i>  <b>Rational:</b> Electronic records are useless unless the lab retains the software and hardware to read and print them out. With the rapid evolution of software/hardware, this is occurring increasingly. It is acceptable to use a third party commercial vendor to access the e-records.	Records that are stored or generated by computers or personal computers (PCs) shall have hard copy or write-protected backup copies. <u>The laboratory must retain the ability to access/use and where appropriate generate hard copies of all records that are retained in electronic format.</u>	The cited current text occurs in 5.12.2.c of the current version. It is a valid point that the backup data is pretty pointless without the ability to access that data. I changed the suggested language to get beyond the simple concept of read/print.  I would agree with the commenter that third parties will likely provide the hardware/software tools to allow this to be done.
10	5.9.4.2.2 f) i. and ii.		Sections 5.9.4.2.2 f) i. and ii. of rev 10.1 have become confusing as they attempt to provide clarification. If the continuing calibration verification (CCV) sample is out of control in either direction, the client samples should be reanalyzed after appropriate corrective action. The existing text in f) is clear on this point and should be retained. If it is necessary to report the client sample data without reanalysis e.g. lack of sufficient sample, there should be no differentiation of the impact of high or low bias in the CCV based on the observed client sample values. It makes no difference if the samples were non-detects, detected but below a regulatory limit/decision level, or detected above a regulatory limit/decision level because ALL the results may be biased based on the CCV performance. The laboratory has a responsibility to reports the facts related to data quality. The client has the responsibility to determine the impact on data utilization. As written, Sections i. and ii. have implicitly intruded into the area of assessment of the impact of the CCV on data quality by specifying		Given the time spent in the initial discussion of this section I'm hesitant to make the suggested change.  However, I would note that this change continues to allow the acquired data to be reported - it simply does make any judgements on the data to be reported based on the possible direction of the bias. The basic question is whether

			<p>what sample data can be reported as a function of direction of the CCV bias, detect/non-detect observations and regulatory limit/decision level. If any data is reported from the analytical batch, then all data must be reported. Appropriate qualifiers must be attached to all data. The client can then interpret the impact on usability.</p> <p><b>Suggested Resolution:</b> Delete the last sentence of section f) and all of sections i. and ii. Replace the deleted text with the following paragraph:</p> <p><i>Sample data obtained after successful corrective action and reanalysis shall be reported with no flags related to CCV performance. If sufficient sample was not available for reanalysis of some samples after recalibration, the original sample data associated with the unacceptable CCV shall be flagged and reported with appropriate discussion in the case narrative. As part of the discussion, in the case narrative, all data obtained on samples from the original batch that were reanalyzed shall be included. This will allow the data user to assess any impact on data quality arising from the failed CCV by comparing the before and after results on samples from the same analytical batch.</i></p>		<p>the ‘penalty’ of reporting flagged data will assure that the laboratory will take the necessary steps to avoid generation of such data in the first place.</p> <p>I would note a problem with the suggested text. It seems to propose that where reanalysis is not possible, i.e. insufficient sample, that it was indeed possible to generate “before and after results”. This scenario seems incongruous with the circumstances presented.</p>
11	<p>D1.1 b) 2) D1.1 b) 3) D1.2</p>	<p>The following sentences are quoted from rev.10.1.</p> <p>D1.1 b) 2) Matrix Spikes (MS), last sentence – Poor performance in a matrix spike may indicate a problem with the sample composition and shall be reported to the client whose sample was used for the spike.</p> <p>D1.1 b) 3) Surrogates, last sentence, Poor surrogate recovery may indicate a problem with the sample composition and shall be reported to the client whose sample produced the poor recovery.</p> <p>D1.2 Matrix Spike Duplicates (MSDs) or Laboratory Duplicates (dups) - Poor performance in the duplicates may indicate a problem with the sample composition and shall be reported to the client whose sample was used for the duplicate.</p>	<p>All three of these quotes attempt to address technical issues associated with matrix effects on sample analysis. They all characterize the issue as a “problem with the sample composition”. NELAC should begin to move beyond this interpretation and address the issue for the complex thing it really is. Each of the “problems” identified above may arise from different sources and laboratories should be encouraged to report the correct interpretations to their clients. The following suggestion provides a means of doing so. The current definitions can mis-communicate the nature of the observations and imply a false impression of the real nature of the sample and/or of laboratory performance.</p> <p><b>Suggested resolution:</b> Replace the phrase “problem with sample composition” with “matrix effect” and add the following definition of matrix effect to Appendix B of the standard.</p> <p><u>Matrix Effect</u> - an effect caused by the sample matrix that obscures the true value of a target analyte in the sample. Matrix effects can cause both positive and negative bias in analytical results. Sources of matrix effects are inherent in the sample and beyond the capability of most analytical methods to correct. Only those methods with specific matrix correction QC procedures, i.e. inductively-coupled plasma analysis for metals, are capable of reporting unbiased results in matrices that interfere with the measurement of target analytes.</p> <p>{Note to the Committee – I agree with Jerry Parr that the use of matrix spikes as a QC criteria is not a valid indicator of data quality and its use should be discouraged by NELAC. I also recognize that MS/MSD are part of the EPA QC folklore and we can’t just drop them. They have value in water analysis but as the matrix changes to soils and solids, a multitude of problems arise. The classic (water) cause of MS/MSD failure (chemical interferences) is overshadowed by the physical properties of the matrix (mostly heterogeneity) that cause the failure. In this case, sample size (mass) may not be large enough to be representative of the heterogeneity of the matrix and/or laboratory sub-sampling may be the source of the variance. Chemically, an MS/MSD may not have the same chemical form as the target analytes in the sample and therefore respond</p>	<p>Where it occurs replace the phrase “problem with sample composition” with “matrix effect” and add the following definition of matrix effect to Appendix B of the standard.</p> <p><u>Matrix Effect</u> - an effect caused by the sample matrix that obscures the true value of a target analyte in the sample. Matrix effects can cause both positive and negative bias in analytical results. The occurrence or extent of the matrix effect may be specific to the analytical method utilized.</p>	<p>The suggested text uses what I consider to be more universal text, “matrix effect” for the exhibited problem and allows the explanation to be better presented in the definitions.</p> <p>However, I disagree with the latter half of presented matrix effect definition. This since it takes a rather critical view of all analytical methods.</p>

			<p>differently than the original analyte to the sample prep and analysis steps.</p> <p>The solution may be found in including an appendix that discusses the correct application and interpretation of MS/MSD. If the committee will consider this approach, I volunteer to be a member or even lead an ad hoc task group to craft the language for the group's consideration. It may be possible to have such a draft in time for consideration at the June meeting if you decide quickly that you would like to have it. }</p>		